

Amendment USPASN 10/021,871 14381/0012

claim language. Thus claim 1 has been amended to read "biologically pure culture" and the Applicant respectfully asserts that this rejection has been traversed.

Claims 28 through 33 were rejected under 35 U.S.C. § 112 second paragraph because the recitation of "administering an effective amount of the probiotic composition" is vague. The Examiner states that it is unclear how the step of administering is to be carried out. The Applicant and the Examiner agreed that amending claim 28 to include the term "orally" before "administering" would traverse this rejection. Thus claim 28 has been amended appropriately.

Claims 15 and 18 were objected to due to a spelling error. Appropriate amendments to the claims have been made. "Anyone" has been replaced with "any one" as required. Thus this objection is traversed.

Claim 20 was objected to because the word "composition" does not follow probiotic in line 1 of claim 20. The appropriate amendment has been made to claim 20 adding the term "composition." Thus this objection is traversed.

#### **Remarks regarding amendment to the specification.**

The amendments are being made pursuant to recommendation of the Examiner based on discussions regarding same during the November 4, 2003 telephone conference. The Applicant attests that no new matter is being added to the specification by these amendments and that their sole purpose is to clarify and more specifically define the invention consistent with the claims and as suggested by the Examiner and her supervisor during the November 4, 2003 interview.

#### **Rejections under 35 U.S.C. §112, first paragraph**

The Examiner has rejected claims 1-33 under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner states that the present invention, a probiotic composition comprising a novel strain of

Amendment USPASN 10/021,871 14381/0012

Lactobacillus casei, cannot be repeatedly isolated and therefore are not readily available to the public. The Examiner notes that the Applicants have made a deposit of their novel Lactobacillus casei strain, however, it is not clear from the specification that the deposit was made pursuant to the Budapest Treaty and has requested that an appropriate declaration of affidavit be made stating that the specific strain will be irrevocably and without restriction or condition be released to the public upon issuance of a patent.

Attached to this amendment is a statement by the attorney of record declaring that the deposit was made in accordance with the Budapest Treaty and the Applicant's specific strain will be irrevocably and with out restriction or condition be released to the public upon issuance of a patent. Moreover, a copy of the American Type Culture Collection (ATCC) "International Form" and viability statement is also attached.

The Applicant respectfully asserts that the statement by the attorney of record and ATCC International Form traverse the Examiners 35 U.S.C. §112, first paragraph rejection.

**Prior Art Rejections under 35 U.S.C. §§102 (b) and/or 103 (a)**

The Examiner has rejected claims 1-6, 8, 11 and 13-19 under 35 U.S.C. §102 (b) as anticipated by or, in the alternative, under 35 U.S.C. 103 (a) as obvious over WO 98/55131 (herein after WO '131).

The Applicant respectfully traverse the prior art rejections under 35 U.S.C. §§102 (b) and/or 103 (a) as anticipated by or in the alternative as obvious over WO 98/55131 (herein after WO '131) for the following reasons. WO '131 does not disclose the strain of Lactobacillus casei (KE01) as presently claimed.

The strain of Lactobacillus disclosed in WO '131 was isolated from infant feces, in contrast KE01 was isolated from a traditional fermented yogurt-like Asian dairy product (see the present specification at page seven, paragraph [0024] lines three). WO'131 repeatedly stresses that the source of the disclosed Lactobacillus sp. was isolated from a 5 day-old infant (page 9 line 37 of WO '131) and that it is "very important

Amendment USPASN 10/021,871 14381/0012

*that the LB21 be isolated from the baby in the first week, such as from the first to eighth day, preferably on the fifth day of living."* (see page 10 lines 2-4 of WO '131)

Furthermore, the cited prior art (WO'131) goes on to emphasize that "...*there is a great difference between different Lactobacillus strains, as is also the case in the subspecies Lactobacillus casei rhamnosus (LB21).* (See page 12 lines 28-30 of WO'131.)

Moreover, the WO'131 reference continues at page 13, lines 5-8 "*A great difference is, for instance, that LB21 has been isolated from the faeces of a baby....*"

Clearly, the WO'131 reference does not disclose the present invention which is Lactobacillus casei strain KE01 having ATCC accession number PTA-3945. The WO'131 reference does not teach isolating a Lactobacillus sp. having probiotic properties from yogurt. In fact WO'131 teaches away from isolating a probiotic organism from sources other than infant feces.

Therefore, because WO'131 does not disclose a probiotic Lactobacillus isolated from yogurt-like products and teaches only Lactobacillus sp. isolated from infant feces, WO'131 does not anticipate Lactobacillus' casei KE01, ATCC PTA-3945. Therefore, WO'131 does not anticipate claim 1 and thus cannot anticipate claims 2-20 which depend from claim 1. Thus the Applicant respectfully asserts that the Examiner's rejection under 35 U.S.C. §102 (b) is traversed.

Furthermore, the Applicant respectfully asserts that the 35 U.S.C. §103 (a) rejection of claims 1-6, 8, 11 and 13-19 as obvious in view of WO'131 is also traversed. As previously discussed, WO'131 teaches away from isolating probiotic compositions from sources other than infant feces. Thus one having ordinary skill in the art would not look to WO'131 for guidance in making the present invention, Lactobacillus casei strain KE01 having ATCC accession number PTA-3945 which was isolated from a yogurt-like product and shown by the present inventor to have excellent probiotic activity.

Moreover, WO'131 does not disclose all of the limitations of the pending claims, specifically, it does not disclose Lactobacillus casei strain KE01 having ATCC accession number PTA-3945.

Amendment USPASN 10/021,871 14381/0012

Additionally persons having ordinary skill in the art would have to engage in undue experimentation without a reasonable probability of successfully isolating Lactobacillus casei strain KE01 based on the teaching of WO'131. For example at page 12 lines 28-30 of WO'131 "...there is a great difference between different Lactobacillus strains, as is also the case in the subspecies Lactobacillus casei rhamnosus (LB21). Furthermore, WO'131 states that "[t]he above-mentioned microorganism strain Lactobacillus casei rhamnosus LB21 was isolated as one of about hundred (sic) lactobacillus strains from feces of an approx. 5-day-old health baby ..." Clearly, WO'131 teaches that one of ordinary skill in the art would need to test hundreds of feces derived isolates in order to identify one having probiotic activity. The inherent unpredictability associated with successfully isolating probiotic organisms is also stated by the present inventor at page 13 paragraphs [0050] and [0051] wherein the present inventor describes testing 81 candidate probiotic lactobacilli before identifying ones having desirable characteristics. Moreover, this inherent unpredictability is recognized by the Examiner in her 35 U.S.C. §112 first paragraph rejection discussed *supra* wherein a biological deposit is required to enable the present invention.

Therefore, the WO'131 fails to establish a prima facie case of obviousness under the meaning of 35 U.S.C. § 103 (a) for the following reasons.

- 1) Persons having ordinary skill in the art seeking to isolate probiotic organisms from yogurt would not be motivated to seek the teachings of a reference (such as WO'131) stating it was essential to isolate probiotic organisms from human infant feces
- 2) There would be no probability of successfully isolating a probiotic organism from yogurt using a teaching stressing the difficulty in isolating a probiotic organism from feces (e.g. WO'131).
- 3) The WO'131 does not teach all of the limitations of the claimed invention. Specifically, it does not teach Lactobacillus casei strain KE01.

Amendment USPASN 10/021,871 14381/0012

Therefore, the Applicant respectfully asserts that based on the foregoing arguments the 35 U.S.C. §103 (a) rejection has been traversed.

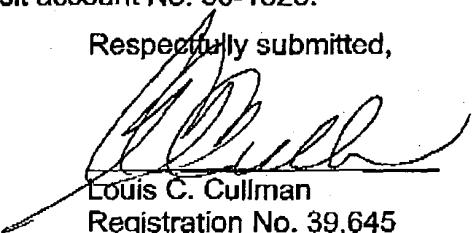
### Conclusion

The Applicant has amended the claims to comply with the Examiner's 35 U.S.C. §112, first and second paragraph rejections. Additionally, the Applicant's attorney of record has provided a statement that Lactobacillus casei strain KE01 PTA-3945 was deposited with the ATCC in accordance with the Budapest Treaty on Intellectual Property. Moreover, the Applicant respectfully asserts that the prior art rejections based on WO 98/55131 have been traversed (both under 35 U.S.C. §§ 102 (b) and 103 (a)). Therefore, the Applicant respectfully asserts that application is now in condition for immediate allowance and requests that Examiner allow this application to pass to issue.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-1329.

Respectfully submitted,

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